

AUG 23 2011



**510(k) Summary of Safety and Effectiveness
Skeletal Dynamics Geminus Volar Distal Radius Plate System**

August 3, 2011

Submitter:

Skeletal Dynamics, LLC
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Contact: Ana M. Escagedo, Vice President
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Establishment Registration Number: 3006742481

Trade Name, Common Name, Classification:

Trade Names	Skeletal Dynamics Geminus Volar Distal Radius Plate System
Common Name	Plate, fixation, bone
Classification	21 CFR §888.3030
Product Code	HRS
Class	Class II

Predicate Devices:

Synthes Titanium Alloy Volar Distal Radius Plate System (K963798)

Description of the Device:

The Skeletal Dynamics Geminus Volar Distal Radius Plate System contains bone plates for the repair of either distal or volar radial fractures. Included in the set are titanium bone screws, fixation pegs, fragment plates, and specialized instrumentation.

The Skeletal Dynamics Geminus Volar Distal Radius Plate is available in 6 sizes and is made of medical grade titanium alloy. Cortical locking screws affix the plate to the diaphysis and fixed angle pegs are used for distal bone fragments. The system is provided non-sterile and is sterilized in the user facility.

The Skeletal Dynamics Geminus Volar Distal Radius Plate System is comprised of:

- titanium alloy plates, washers and screws
- stainless steel K-wires (for provisional fixation not for implantation)
- system specific instrumentation.

Intended Use:

The Skeletal Dynamics Geminus Volar Distal Radius Plate System is intended for fixation of fractures and osteotomies of the distal radius.

Summary of Technological Characteristics / Substantial Equivalence:

The substantial equivalence of the Skeletal Dynamics Geminus Volar Distal Radius Plate System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging, and does not present any new issues of safety or effectiveness.

Performance Testing:

Preclinical analysis and cadaveric testing demonstrated that the Skeletal Dynamics Geminus Volar Distal Radius Plate System is substantially equivalent to the predicate device which is currently marketed. Mechanical testing which established equivalency included static, fatigue and dynamic testing. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:

The Skeletal Dynamics Geminus Volar Distal Radius Plate System is substantially equivalent to the predicate device identified in this premarket notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Skeletal Dynamics, LLC
% Ms. Ana Escagedo
8905 SW 87th Avenue
Suite 201
Miami, Florida 33176

AUG 23 2011

Re: K111620

Trade/Device Name: Skeletal Dynamics Geminus Volar Distal Radius Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 2, 2011
Received: August 4, 2011

Dear Ms. Escagedo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111620

Device Name: Skeletal Dynamics Geminus Volar Distal Radius Plate System

Indications For Use: The Skeletal Dynamics Geminus Volar Distal Radius Plate System is intended for fixation of fractures and osteotomies of the distal radius.

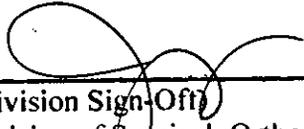
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

for Mr. McKeown
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